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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,467	12/11/2001	Walter Sebald	086033-000000US	2473

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EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT PAPER NUMBER

1647

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/913,467	SEBALD, WALTER	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2006 and 04 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 10 is/are allowed.
- 6) ☒ Claim(s) 2-9, 11-23, and 25-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Withdrawal of Finality***

1. Pursuant to the telephonic interview of 4 October 2006, Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Rejoinder of Claims 3 and 10***

2. Applicant asserts that amended claims 3 and 10 should be rejoined and examined along with claims 1-2, 4-9, 11-23, and 25-28. Amended claims 3 and 10 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 3 is drawn to SEQ ID NO: 3 or SEQ ID NO: 4, in the alternative. Claim 10 is drawn to SEQ ID NO: 5 or SEQ ID NO: 6 in the alternative. Applicants argue that claims 3 and 10 were improperly withdrawn from consideration in light of the Office Action of 29 September 2004, indicating that claims 3 and 10 were objected to, but otherwise allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. It is noted that the restriction requirement, electing claims 1-26, as drawn to SEQ ID NO: 1, was made final in the Office Action of 29 September 2004 (see p. 2 of the Office Action, second full paragraph). Claim 3 is drawn to SEQ ID NOs: 3 or 4, in the alternative. SEQ ID NO: 3 meets the limitations of the formula of SEQ ID NO: 1, and SEQ ID NO: 4 meets the limitations of the formula insofar as it is a tandem repeat (an oligopeptide) of SEQ ID NO: 1. Applicant argues that because SEQ ID NO: 4 is merely a tandem repeat of the generic formula provided in claim 1, the search of sequences of the formula of claim 1 would encompass a search of SEQ ID NO: 4. Applicant's arguments have been fully considered and are persuasive.

3. Similarly, claim 10 is drawn to SEQ ID NOs: 5 and 6 in the alternative. SEQ ID NO: 5 is a 120 amino acid polypeptide and SEQ ID NO: 6 is a 124 amino acid polypeptide. Applicant argues that the amino acid sequence of SEQ ID NOs: 5 and 6 comprises the amino acid sequence of SEQ ID NO: 1 and thus, a search of SEQ ID NOs: 5 and 6 would be encompassed within a search of SEQ ID NO: 1. Applicant's argument has been fully considered, and is found to be persuasive. Claims 3 and 10 are hereby rejoined.

***Formal Matters***

4. Claims 1-23, and 25-28 are under examination. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

***Claim Objections/Rejections Withdrawn***

5. The rejections of claim 29 are moot in light of Applicant's cancellation of the claim.
6. The rejection of claims 1, 2, 4-9, 11-23, and 26-28 under 35 U.S.C. 112, first paragraph, as lacking enablement, are withdrawn in light of Applicant's amendments, filed 5 April 2006.
7. The rejection of claims 1, 2, 4-9, 11-23, and 25 under 35 U.S.C. 112, first paragraph, as lacking written description are withdrawn in light of Applicant's amendments, filed 5 April 2006.
8. The rejection of claims 1, 2, 4-7, 9, and 11-23, and 25-27 under 35 U.S.C. 102(e) as being anticipated by Hubbell et al., U.S. Application publication number 2001/0020086 (now US Patent 6,960,452, issued 1 November 2005, priority to 27 August 1998) (the '086 application, previously cited in the Office Actions of 29 September 2004, 17 June 2005, and 5 January 2006) are withdrawn.

Applicant argues that Hubbell et al., teach the addition of heparin binding domains to polypeptides not previously comprising any heparin binding domains. Applicant distinguishes the instant invention by arguing that the instant claims are drawn to polypeptides initially comprising heparin binding domains wherein additional heparin binding domains are added. Applicant's arguments have been fully considered and are found to be persuasive. Hubbell et al. does not specifically disclose BMP, GDF, or BMP-2. For these reasons, the anticipation rejection is withdrawn.

9. The rejection of claims 1, 2, 4-9, 11-23, and 25-28 under 35 U.S.C. 103 as being unpatentable over Hubbell et al., U.S. Application publication number 2001/0020086 (the '086 application; now US Patent 6,960,452, issued 1 November 2005, priority to 27 August 1998) (previously cited in the Office Actions of 29 September 2004, 17 June 2005, and 5 January 2006), in view of Ruppert *et al.*, Eur J. Biochem 1996 Apr 1; 237(1):295-302, (previously cited in the Office Action of 5 January 2006), is withdrawn. Applicant's arguments have been fully considered and are found to be persuasive. Hubbell et al., does not specifically disclose BMP, GDF, or BMP-2. Additionally, Hubbell teaches the addition of

Art Unit: 1647

heparin binding domains only to growth factors that do not naturally contain heparin binding domains. As such, Hubbell fails to provide motivation to add heparin binding domains to those proteins that already have them. For these reasons, the rejection is withdrawn.

10. The rejection of claims 1 and 8 under 35 U.S.C. 103 as being unpatentable over U.S. Application publication number 2001/0020086 (the '086 application (now US Patent 6,960,452, issued 1 November 2005, priority to 27 August 1998) in view of Linkhart *et al.*, (previously cited in the Office Actions of 29 September 2004, 17 June 2005, and 5 January 2006) is withdrawn for the reasons stated above.

***New Claim Rejections- Necessitated by Amendment***

***Claim Rejections - 35 USC § 112, First Paragraph***

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions as set forth below, does not reasonably provide enablement for all pharmaceutical compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claim recites a pharmaceutical composition comprising the polypeptide variant of claim 1. The claim has no clear requirement for any pharmaceutically acceptable carrier or excipient. When the term "pharmaceutical" is used in the preamble of a claim, its intended use as a pharmaceutical must be shown. The intended use of the claim as a pharmaceutical is imputed to mean every intended use, including use as a preventative, because the claim, as written, fails to limit any such intended use.

The specification does not reasonably provide enablement for prophylaxis (prevention) of any disease in any species by administration of the pharmaceutical of claim 1 by any means. The skilled artisan cannot envision the prevention of any disease by administration of the pharmaceutical of claim 1 by any means. Prevention involves "attacking" the underlying cause of disease; i.e., disrupting the mechanisms which give rise to the disease. The skilled artisan is aware that the causes and/or etiology of all diseases or even the genera of growth factor- involved diseases were unknown at the time of the invention herein. For purposes of enablement, the specification must provide reasonable detail in order for those skilled in the art to carry out the invention. In this case, the specification must disclose a means of

Art Unit: 1647

preventing growth factor- involved diseases, regardless of the underlying cause(s). The teachings of the specification do not enabled a person of ordinary skill in the art to make and use the claimed pharmaceutical in a method of prophylaxis. Moreover, "[p]atent protection is granted only in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d at 1366, 42 USPQ2d at 1005 (Fed. Cir.), cert. denied, 118 S. Ct. 397 (1997), ("Tossing out the mere germ of an idea does not constitute an enabling disclosure").

***Claim Rejections - 35 USC § 112, Second Paragraph***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant uses the phrase "essentially the same receptor binding affinity" in the amended claim, but fails to establish the metes and bounds of the phrase. "Essentially the same" receptor binding affinity could vary greatly or could mean no receptor binding affinity at all. It is noted that there are different binding affinities between T3, T4, and BMP-2 in Figure 4.

15. Claims 2, 4-9, 11-15, 17-23, and 25-28 are is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the article "a" in the preamble. The proper article to use, when referring back to a polypeptide, a nucleic acid, or a host cell, for example, that has been claimed in a preceding claim, is "the." The use of the article "a" in dependent claims broadens the scope of potential polypeptides, for example, that may be read into a particular recitation of a claim. This rejection may be overcome by changing "a" to "the".

16. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a pharmaceutical composition comprising a BMP or GDF polypeptide variant as recited in claim 1. When the term "pharmaceutical" is used in the preamble of a claim, its intended use as a

Art Unit: 1647

pharmaceutical must be shown. The intended use of the claim as a pharmaceutical is imputed to mean every intended use, including use as a preventative, because the claim, as written, fails to limit any such intended use.

*Conclusion*

17. Claims 1 and 10 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CMW

AU 1647

*Marianne P. Allen*

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PRIMARY EXAMINER

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